GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:285
ANSWERED ON:18.12.2015
Hepatitis
Kirtikar Shri Gajanan Chandrakant;Mahato Shri Bidyut Baran

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether cases of hepatitis infections are on the rise in the country, if so, the details thereof and the reasons therefor;

(b) the number of cases of various types of hepatitis infections reported during each of the last three years and the current year, type and State/UT-wise;

(c) the measures taken/proposed to be taken by the Government for prevention and control of hepatitis along with the funds allocated and utilised for the purpose during the said period, State/UT-wise;

(d) whether the Government has recently granted a waiver of local trials for certain new direct-acting antiviral drugs treating the disease, if so, the details thereof and the reasons therefor along with the benefits accrued therefrom; and

(e) the steps taken/proposed to be taken by the Government to ensure the quality and safety of the anti-hepatitis drugs?

Answer

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)

(a) to (e): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA
STARRED QUESTION NO. 285* FOR 18TH DECEMBER, 2015

(a) to (c) The number of cases due to Viral Hepatitis as reported by the States/UTs to Central Bureau of Health Intelligence (CBHI) in the last three years is given at Annexure I. Separate figures for various types of Hepatitis are not collected at present.

The main cause of Hepatitis A & E is consumption of contaminated water and provision of safe drinking water is the main strategy to control diseases caused by drinking of contaminated water. Rural water supply is a State subject. Government of India supplements the efforts of the States by providing technical and financial assistance under the centrally sponsored National Rural Drinking Water Programme (NRDWP) for providing safe and adequate drinking water supply facilities in rural areas of the country.
Hepatitis B vaccination is included under the Universal Immunization Programme (UIP) of Government of India. Government is using auto-disabled (AD) syringes for all vaccinations under the UIP in all States. AD syringes are single use, self-locking syringes that cannot be used more than once. This prevents misuse and contamination/cross infection through repeated use of unsterile injection/equipment. The funds released to the States for implementation of UIP in last three years and current year are placed at Annexure II.
Screening of blood reduces the risk of transmission of Hepatitis B and C by blood transfusion. Therefore, blood banks mandatorily screen for Hepatitis B & C as per Drug & Cosmetics Act 1940 and rules thereof.
A National Programme on Surveillance of Viral Hepatitis under the 12th Five Year Plan has been launched by the Government. National Centre for Disease Control (NCDC), Delhi has been identified for coordinating the various activities under this programme.
NCDC, under the Ministry of Health and Family Welfare, provides technical guidance to State Governments on prevention and control of water borne diseases including Hepatitis, and helps them in carrying out investigation of outbreaks of such diseases under Integrated Disease Surveillance Programme (IDSP). NCDC also provides laboratory support for outbreak investigations and etiological diagnosis besides conducting regular training courses for development of trained manpower. Funds are released to States/UTs under Integrated Disease Surveillance Programme (IDSP) to strengthen surveillance and to detect and respond to

outbreaks of epidemic-prone diseases. The details of funds released to States/UTs during last three years and current year are at Annexure- III.

(d) The following three antiviral drugs have been approved in 2015 considering waiver of local clinical trial for Import/Manufacturing and marketing in the country.

S. No Name of the Drug Date of Approval

01 Sofosbuvir 400 mg Tablet 13.01.2015
02 FDC of Ledipasvir (90 mg) + Sofosbuvir 400 mg) Tablet 08.12.2015
03 Daclatasvir Tablet (30 mg/ 60 mg) 11.12.2015

The issue of considering waiver of local clinical trial in above cases were deliberated in the expert committees and, based on their recommendation, waiver of local clinical trial was granted.
Grant of waiver of local clinical trial has resulted in early launch of the drug Sofosbuvir indicated for "in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults".
These antiviral drugs have been approved for Import/ Manufacturing and marketing in the country subject to certain conditions. One of the conditions is that the applicant shall conduct a time bound Post Marketing Trial (Phase-IV) as per the protocol approved by DCG (I).

(e) Drugs including anti-hepatitis are regulated under the provisions of Drugs and Cosmetics Act, 1940 and Rules 1945 made thereunder.

1. Under the Act and Rules, the regulatory control over the drugs imported into the country is exercised by the Central Government through the Central Drugs Standard Control Organization (CDSCO). For import and marketing of drugs, the overseas manufacturing premises and the drugs are required to be registered and license is required to be obtained from CDSCO.

2. New drugs are approved in accordance with provision of the Drugs and Cosmetics Act, 1940 and Rules, 1945 made thereunder after being satisfied that the drug permitted to be imported/ manufactured shall be effective and safe for use in the country

3. Detailed requirements and guidelines for manufacture/import of new drugs in the country are specified under Rule 122A, 122B, 122D, 122E and Schedule Y of Drugs and Cosmetics Act, 1940 and Rules, 1945.

4. However, for manufacture/Import and marketing of any new drug, prior permission from CDSCO is required to be obtained.

5. The manufacture, sale and distribution of drug is regulated under the said Act & Rules by the State Drugs Control Authorities appointed by the State Governments. The regulatory control over the manufacture and sale of the drugs is exercised through a system of licensing and inspection.
Government has launched Pharmacovigilance Programme of India for monitoring the safety of the marketed drug. Indian Pharmacopoeia Commission, Ghaziabad, is the national co-coordinator of the programme.

Annexure I

State-wise Cases due to Viral Hepatitis (All Causes) during 2012 − 2015

Sl. No.	State / U.T.	2012 Cases	2013 Cases	2014(Prov.) Cases	2015(Prov.) Cases	Reference Period
1	Andhra Prad.	7955	8739	3716	1867	Jan 15 up to August,15
2	Arun. Prad.	1520	588	378	218	September,15
3	Assam	419	466	1994	456	September,15
4	Bihar	3094	6736	20670	20361	October,15
5	Chhattisgarh	914	670	533	437	October,15
6	Goa	92	173	182	102	July, 15
7	Gujarat	4763	3676	4808	2870	October,15
8	Haryana	2686	1307	2717	4076	October,15
9	HP	1310	2023	2808	1440	September,15
10	J & K	5967	6307	5110	3172	October,15
11	Jharkhand	983	1444	972	457	October,15
12	Karnataka	10789	5415	6613	5001	October,15
13	Kerala	8212	7034	5567	2961	October,15
14	Madhya Prad.	12325	14055	16141	8802	October,15
15	Maharashtra	6175	5851	5985	5776	October,15
16	Manipur	229	258	443	68	September,15
17	Meghalaya	221	518	609	253	June, 15
18	Mizoram	914	419	194	155	October,15
19	Nagaland	284	119	88	27	October,15
20	Orissa	5372	3743	4910	3040	October,15
21	Punjab	3323	3099	4525	7551	October,15
22	Rajasthan	1595	2384	9719	2194	October,15
23	Sikkim	667	692	554	18	September,15
24	Tamil Nadu	10628	1868	2671	858	October,15
25	Tripura	272	205	177	85	September,15
26	Uttarakhand	6499	8619	9243	7529	September,15
27	Uttar Pradesh	6345	9079	16026	8783	October,15
28	West Bengal	4097	4967	4444	2951	October,15

29 A & N Islands 172 231 262 37 August,15 exc Feb, May
30 Chandigarh 1751 424 766 862 August,15
31 D & N Haveli 159 90 32 43 October, 15 exc Aug
32 Daman & Diu 192 184 65 51 October,15 exc Mar, Apr
33 Delhi 8184 8290 6425 4872 August,15
34 Lakshadweep 17 5 16 4 September,15
35 Puducherry 755 447 299 435 September,15
Total 118880 110125 139662 97812
Source: National Health Profile brought out by CBHI, DGHS
Note :
1. 2014 & 2015 : Andhra Pradesh excludes data of 10 districts of Telangana from July 2014 Onwards.
2. 2014: Data for Assam till September
3. 2014 : Data from Meghalaya does not contain figures for October

Annexure II
Allocation ,Release & Expenditure under Routine Immunization for the12th Plan
Rs. In crore

S.N. States	2012-13			2013-14			2014-15			2015-16		
	Allocation	Release	Exp	Allocation	Release	Exp	Allocation	Release	Exp	Allocation	Release	Exp
1 Andaman & Nicobar Islands	0.06	0.04	0.06	0.06	0.03	0.03	0.07	0.06	0.02	0.06	0.04	0.02
2 Andhra Pradesh	12.66	10.00	19.67	14.06	6.22	7.17	9.54	0.00	4.49	7.63	0	4.92
3 Arunachal Pradesh	0.68	0.61	1.54	0.76	1.76	1.87	0.76	0.57	0.47	0.61	0.45	0.44
4 Assam	15.38	12.38	24.99	17.09	12.82	18.56	17.09	12.82	13.36	13.67	10.25	8.41
5 Bihar	20.17	37.21	28.05	22.41	28.87	48.18	20.05	15.04	59.12	16.04	12.03	7.21
6 Chandigarh	0.16	0.00	0.03	0.18	0.03	0.12	0.20	0.15	0.07	0.16	0.16	0.11
7 Chattisgarh	5.73	0.00	7.33	6.36	3.50	10.24	4.93	3.70	8.95	3.95	2.96	5.02
8 Dadra & Nagar Haveli	0.05	0.02	0.06	0.06	0.06	0.07	0.07	0.00	0.13	0.05	0.04	0.07
9 Daman & Diu	0.04	0.00	0.03	0.04	0.04	0.07	0.05	0.04	0.07	0.04	0.03	0.01
10 Delhi	2.50	2.05	0.46	2.78	0.69	1.21	3.24	3.24	2.68	2.59	1.94	4.00
11 Goa	0.22	0.00	0.10	0.24	0.07	0.07	0.28	0.21	0.10	0.23	0.12	0.04
12 Gujarat	9.03	24.90	23.75	10.03	14.37	24.42	11.67	11.67	26.27	9.33	7.00	12.27
13 Haryana	3.79	6.79	7.49	4.21	3.16	12.74	4.90	3.67	10.57	3.92	2.94	8.74
14 Himachal Pradesh	1.54	0.85	1.77	1.71	1.28	0.89	1.32	0.99	1.14	1.06	0	1.86
15 Jammu & Kashmir	2.81	0.00	1.68	3.13	0.94	1.63	2.42	0.00	0.90	1.94	1.46	0.84
16 Jharkhand	7.39	0.00	10.54	8.21	6.16	14.70	6.37	4.78	17.18	5.10	3.83	9.85
17 Karnataka	9.14	6.85	8.39	10.15	3.89	10.53	11.81	11.81	11.30	9.45	7.09	5.55
18 Kerala	4.99	3.74	6.95	5.55	4.16	7.80	6.45	4.84	8.13	5.16	3.87	3.43
19 Lakshadweep	0.01	0.09	0.04	0.01	0.05	0.06	0.01	0.01	0.01	0.01	0.01	-
20 Madhya Pradesh	14.11	14.11	43.97	15.68	11.76	44.01	14.03	10.52	37.28	11.22	10.10	17.99
21 Maharashtra	16.80	12.60	30.47	18.67	16.06	32.86	21.71	16.28	31.21	17.37	13.03	10.61
22 Manipur	1.34	1.34	0.72	1.49	0.86	0.71	1.49	1.12	0.66	1.19	0.90	0.42
23 Meghalaya	1.46	1.28	0.57	1.63	0.04	0.31	1.63	0.00	0.73	1.30	0.98	0.46
24 Mizoram	0.55	0.51	0.59	0.60	0.61	0.55	0.60	0.14	0.30	0.48	0.36	0.30
25 Nagaland	0.98	0.76	1.23	1.09	0.73	1.30	1.09	0.81	0.19	0.87	0	0.68
26 Orissa	8.15	0.00	12.89	9.06	9.06	18.66	8.10	8.10	17.36	6.48	4.86	6.65
27 Pondicherry	0.18	0.14	0.12	0.21	0.09	0.12	0.24	0.24	0.11	0.19	0	0.07
28 Punjab	4.14	2.68	4.27	4.60	3.45	6.93	5.35	4.01	7.75	4.28	3.21	6.65
29 Rajasthan	13.34	20.92	19.90	14.82	11.11	23.71	13.26	9.94	28.10	10.61	7.96	12.12
30 Sikkim	0.30	0.19	0.26	0.33	0.26	0.45	0.33	0.25	0.53	0.27	0.20	0.18
32 Tamil Nadu	10.78	0.00	2.18	11.98	12.75	6.32	13.94	13.94	8.01	11.15	0	4.33
33 Tripura	1.81	0.00	1.05	2.01	1.33	1.53	2.01	1.51	3.09	1.61	1.21	0.56
34 Uttar Pradesh	38.79	60.40	78.82	43.10	0.00	112.85	38.56	28.92	93.16	30.85	23.14	43.07
35 Uttarakhand	2.27	0.00	3.47	2.52	1.88	5.36	1.95	1.47	5.18	1.56	1.17	4.17
36 West Bengal	13.65	1.25	17.14	15.17	30.80	25.96	17.65	13.24	26.98	14.12	10.59	17.68
37 Telangana	6.82	5.11	4.46	5.45	0	4.76						
Grand total	225.00	221.70	360.57	250.00	188.91	441.94	250.00	189.19	430.05	200.00	131.93	203.52
38 Others	0.00	0.00	2.85	0.00								
Grand total	225.00	221.70	363.42	250.00	188.91	441.94	250.00	189.19	430.05	200.00	131.93	203.52

Note:
1). Expenditure includes expenditure against central Release, state release & unspent balances at the beginning of the year. Expenditure for the F.Y. 2015-16 (upto 30.09.2015 as per FMR) are provisional.
2). Release for the F.Y. 2015-16 is updated upto 30.10.2015 and is provisional
3). The above Releases relate to Central Govt. Grants & do not include state share contribution.

Annexure III

INTEGRATED DISEASE SURVEILLANCE PROGRAMME
SUMMARY OF FINANCIAL STATUS OF STATE SOCIETIES (Rs in Lacs)
As on 05.11.2015

Sl. No.	States/UTs	GIA Released to States				Expenditure			
		2012 - 13	2013-14	2014-15	2015-16	2012 - 13	2013-14	2014-15	2015-16
1	Andhra Pradesh	104.29	198.31	122.48	181.84	229.84	167.45	40.37	
2	Gujarat	205.4	270	400	243.75	311.27	490.55	509.78	64.44
3	Karnataka	214.22	124	270.5	180	214.65	298.58	367.91	175.35
4	Maharashtra	100	183.5	280	210.43	210.2	195.21	55.01	
5	Punjab	198.96	120.2	168.75	115	173.2	223.18	282.1	124.93
6	Rajasthan	231.77	195.32	325	225	214.92	293.04	471.03	121.25
7	Tamil Nadu	60	98.26	325	213.75	143.29	287.2	350.6	156.87
8	Uttarakhand	90.87	60.93	45	115.33	160.97	177.72	26.54	
9	West Bengal	151.67	120.11	250	100	200.83	221.81	181.73	44.91
10	Andaman & Nic. Islands	19.87	9	5.25	11.27	6.43	6.06	3.31	
11	Bihar	147.35	164.69	200	167.56	190.84	200.94	11.5	
12	Chandigarh	7.03	19.92	40	23.25	14.66	28.31	30.53	18
13	Chhattisgarh	96.74	29.67	60	100	65.86	89.49	130.22	20.88
14	Dadra & N. Haveli	22.36	21	13.5	15.04033	23.96	27.79	18.38	
15	Daman & Diu	31.32	6.01	22.5	15.59	31.41	24.7433	9.11	
16	Delhi	34.9	56.25	63.75	33.22	56.51	90.6	36.28	
17	Goa	18.02	28.23	45	20	21.94	33.62	43.78	21.35
18	Haryana	220.35	71.32	150	135	134	169.1	181.25	
19	Himachal Pradesh	28.34	73.06	70	52.5	46.56	56.98	63.2	10.67
20	J&K	50	82.22	127.5	150	94.71	119.09	129.72	11.79
21	Jharkhand	119.25	112.5	100	91.05	137.49	157.54	23.01	
22	Kerala	23.84	106.21	101.25	112.5	106.44	147.61	131.19	47.7
23	Lakshadweep	1.13	0.82	3.13	0.39				
24	Madhya Pr.	120.65	246.51	350	225	245.12	340.66	359.59	167.53
25	Orissa	118.3	92.72	350	150	146.48	247.08	310.14	
26	Puducherry	30	43.6	70	48.75	45.17	60.07	61.26	28.76
27	Uttar Pradesh	203.88	300	225	344.89	178.35	478.01		
28	Telangana	0	0	87.53	93.75	0	0	98.23	71.73
29	Arunachal Pr.	94.21	181.69	152.24	107.87	201.23	131.03	114.84	
30	Assam	170.41	129.91	206.25	262.5	176.92	220.37	296.54	63.72
31	Manipur	42.6	25.69	96.25	50	55.26	41.88	84.07	4.95
32	Meghalaya	59.54	20.25	45	50	34.01	56.96	47.84	
33	Mizoram	36.53	70.44	97.5	75	66.01	84.07	80.23	13.44
34	Nagaland	60.3	115.84	120	112.5	113.47	127.01	112.57	38.89
35	Sikkim	20.87	30	50	30	28.81	38.12	48.42	9.61
36	Tripura	15.32	50	30	16.38	23.61	44.94	7.12	
Sub Total OTNE		2217.8	2760.36	4342.77	2618.25	3366.45033	4333.19	5231.4533	1310.06
Sub Total NE		484.46	589.14	817.24	610	598.73	793.25	845.64	252.57
Grand Total		2702.26	3349.5	5160.01	3228.25	3965.18033	5126.44	6077.0933	1562.63